

**UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA**

**URL PHARMA, INC., MUTUAL
PHARMACEUTICAL COMPANY, INC. AND
UNITED RESEARCH LABORATORIES, INC.,**

Plaintiffs,

-against-

RECKITT BENCKISER INC.,

Defendant.

Case No. 15-cv-00505(PBT)

Hon. Petrese B. Tucker

**REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF MOTION
BY DEFENDANT RECKITT BENCKISER TO DISMISS THE COMPLAINT**

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ARGUMENT

I. Mutual's¹ Antitrust Claims Under Sherman Act § 2 Fail As a Matter of Law

Mutual's attempt to extract *in terrorem* treble damages under the antitrust laws by leveraging a garden-variety breach of contract claim fails to state a claim for relief as a matter of law. Since 2007, the Supreme Court, as set forth in *Twombly* and its progeny, has set forth new standards by which such antitrust complaints are adjudged.² Mutual has not and cannot plead its way around the well-settled legal principle that a breach of contract claim does not give rise to antitrust violations. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993) (“Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws; those laws do not create a federal law of unfair competition...”). Mutual's reliance upon outdated pleading standards and inapplicable law is just the first of several reasons why this action should be dismissed:

1. Mutual admits it could have entered the market on its own. Mutual omits critical terms of the Settlement Agreement that demonstrate that it was not barred from the market by RB. The Settlement Agreement allowed Mutual to bring its own line of Generic ERG products to market when it obtained FDA approval of its ANDA No. 78-333 (“Mutual ERG”). The SA expansively covered Mutual ERG products containing 600 mg Guaifenesin, 1200 mg Guaifenesin, and Combination Guaifenesin Products within the term “Licensed Products” (SA WHEREAS Clause 2, ¶¶ 1(n), 1(s), 5(a)). Mutual has had eight years to get Mutual ERG

¹ All capitalized terms have the same meaning as those in the Moving Brief.

² Mutual erroneously cites *Hospital Building v. Trustees of Rex Hosp.*, 425 U.S. 738 (1976) (Opp. Br. 6, 11) for the now outdated, liberal pleading rule in antitrust cases founded upon *Conley v. Gibson*, 425 U.S. 738, 746 (1976). *Conley* was expressly abrogated in 2007 by *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 561-63 (2007). Since *Twombly*, courts have stopped overzealous plaintiffs from pursuing implausible antitrust lawsuits because of the costly burden and discovery imposes upon litigants and the courts. *Id.*

approved. Had Mutual succeeded, RB could do nothing to stop Mutual ERG from entering the marketplace. Thus, the only party responsible for Mutual's current inability to sell ERG is Mutual. Second, no one forced Mutual to settle its patent infringement lawsuit. In exchange for receiving RB's grant of two licenses to compete and sell its own line of Licensed Products (SA ¶¶ 5(a),(b)(i), (ii), Mutual agreed not to challenge the validity of the Mucinex patent and to stay out of the market for five years (Opp. Br. at 1: "The Agreement included a promise by Mutual not to challenge Reckitt's Mucinex monopoly by selling its alleged non-infringing ERG product for at least five (5) years..."). This wasn't "leverage" as Mutual contends (Opp. Br. at 12); rather it was a logical result of having Mutual's patent counsel negotiate at arm's length and draft the Settlement Agreement, which set forth the clear conditions prior to Mutual's entry into the market (SA ¶¶ 5(a) and (b)). Mutual's argument that RB thwarted its entry into the market lacks the necessary plausible factual basis to support its claims.

2. No monopolization or attempt to monopolize has been pled as a matter of law.

Significantly, Mutual admits that its antitrust claims rest on RB's alleged refusal to supply a product (Opp. Br. at 6 (RB "refuses to meet its supply obligations to Mutual"), 11 ("Reckitt's repudiation of the Settlement Agreement has prevented Mutual from entering the ERG market")), thereby excluding Mutual from the market. This is the classic, paradigmatic "refusal to supply" or "refusal to deal" case, just like *Adderall*, which does not give rise to an antitrust claim outside of rare circumstances not present here. 754 F.3d at 135 ("The mere existence of a contractual duty to supply goods does not by itself give rise to an antitrust 'duty to deal.'"). The Settlement Agreement here, as in *Adderall*, on its face ended RB's monopoly of the Mucinex patent when triggered by Mutual's ANDA approval or its compliance with the conditions set forth in the ¶¶ 5 (b)(ii), 6 of the Agreement. Mutual's claims thus essentially rely upon and are

predicated upon a refusal to deal framework for the required allegations of exclusionary conduct. Since the Settlement Agreement does not give rise to an antitrust duty to deal, and RB is otherwise permitted to have a monopoly under the patent laws (*see* Mov. Br. at 7-8), Mutual's antitrust claims fail as a matter of law.³

3. This is not an *Actavis* reverse-payment case. The Settlement Agreement did not provide Mutual with **any** payment—much less a large payment—to stay off the market.⁴ (*See* SA WHEREAS Clause 11 at 2.) Mutual agrees, as it states: “In particular, the Agreement did not involve a “reverse payment” requiring Reckitt to pay Mutual to stay off the market” (Opp. Br. at 17). Therefore, the Settlement Agreement is not the type with which the Supreme Court was concerned in *Actavis*, where the patentee plaintiff pays the infringing defendant. *FTC v. Actavis, Inc.*, 133 S.Ct. 2223, 2233 (2013). And even if it were, under that scenario Mutual

³ For these reasons, Mutual's reliance on Sherman Act Section 1 conspiracy cases is misplaced. *See United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) (cited at Opp. Br. 14) (patentee part of a conspiracy to restrain trade); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) (cited at Opp. Br. 14) (patentee part of a price fixing conspiracy); *United States v. New Wrinkle Inc.*, 342 U.S. 371, 379-80 (1952) (cited at Opp. Br. 15) (same). Mutual nowhere alleges that RB conspired with any other company to create a horizontal monopoly. Similarly, its reliance on a Fourth Circuit patent infringement case fails, as that too, was a horizontal conspiracy case. *Int'l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 429 (4th Cir. 1986) (cited at Opp. Br. 13) (rejecting notion that patent holder has the right to conspire with other licensees to wrongfully terminate a licensee with the express aim of recreating the patent monopoly). That case, like the rest Mutual cites, has no bearing or applicability here.

⁴ While there is some disagreement in the Third Circuit as to whether a reverse payment must be cash or may be some other kind of valuable consideration, *compare In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 568-69 (D.N.J. 2014) (must be cash); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410 at *21-22 (D.N.J. Oct. 6, 2014) (need not be cash), all *Actavis* claims with non-cash payments that have survived a motion to dismiss have involved unjustified payments (i.e., money) for other goods and services that were inexplicably tied into the settlement. *See, e.g., In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751-53 (E.D.Pa. 2014) (finding two agreements—one to pay royalties on the sales of the drug and another drug not at issue, and one to pay the generic company to be a “back up” manufacturer—to be the type of large, unjustified reverse payments targeted in *Actavis*). No such payment is provided for in the SA or occurred here.

would be RB's co-conspirator, not a victim of illegal constraint of trade. *See, e.g., id.* at 2227 (FTC sued both Actavis and the other settling parties as co-conspirators).⁵

4. Mutual does not and cannot plead a plausible relevant market. Mutual offers no coherent answer to the law (cited in RB's Mov. Br. at 13-15) demonstrating that the pleading contains a facially implausible relevant market. In effect, Mutual claims that someone with a cold will let her illness go untreated rather than select one of some 1500 other immediate-release guaifenesin competitors. Such readily available cold relief medications containing either ERG or IRG are sold in proximity to each other. The relevant market of only Mucinex, therefore, is implausible and unsupported. In response, Mutual attempts to rely upon single-product prescription drug cases, where it is accepted that a doctor prescribes the most effective medicine with little thought to competing costs.⁶ *SmithKline v. Eli Lilly & Co.* is thus, distinguishable for the same reason. 575 F.2d 1056, 1063 (3d Cir. 1978) (cited at Opp. Br. 9) ("Prescribing physicians are not cost-conscious in their choices of an antibiotic for a hospitalized patient, and so do not opt for a less expensive over a more costly medication."). And in desperation, Mutual argues that RB has "concede(d) market power in the ERG market" (Opp. Br. at 8), when all RB

⁵ Mutual cites other *Actavis* cases which also do not apply. *See In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367 (D. Mass. 2013) (wholesale drug distributors, direct purchasers and end-payors brought class actions against both brand-name manufacturer and settling generic manufacturers for reverse-payment conspiracy); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 2015 WL 356913 (E.D. Pa. 2015) (direct purchasers, end payors, and the FTC sued brand name pharmaceutical company and generic drug manufacturers for antitrust conspiracy).

⁶ *See In re Nexium Antitrust Litig.*, 968 F. Supp. 2d 367, 387 (D. Mass. 2013) (cited at Opp. Br. 8) (relevant market is a prescription drug and its generic); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680 (E.D. Mich. 2000) (cited at Opp. Br. 8) ("once a physician prescribes Cardizem CD, a consumer patient may only purchase Cardizem CD or its FDA-approved AB-rated bioequivalent"); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n. 40 (S.D. Fla. 2005) (cited at Opp. Br. 10) (though unnecessary dicta, court finds relevant market is prescription drug Hytrin and "its generic bioequivalent forms"); *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08-03710, 2010 WL 1222012 at *6 (S.D.N.Y. Mar. 29, 2010) (cited at Opp. Br. at 9) ("Here, Sandoz has posited two separate product markets based on two drugs that rely on the same active ingredients.... On its face, this is implausible and irrational.").

pointed out in its opening brief (and Mutual concedes) is that Mutual agreed not to challenge RB's patent in settlement (citing Settlement Agreement ¶ 8), that RB thereby has not violated nor expanded "the four-corners of a lawfully-granted patent monopoly" (Mov. Br. at 7). Without a plausible relevant market, Mutual's antitrust claims fail as a matter of law.

5. Mutual has not suffered antitrust injury and therefore lacks antitrust standing.

Mutual is clearly not damaged by any alleged overcharges for the Mucinex product. (*See* Compl. ¶¶ 33-34; Opp. Br. at 11-12.) Mutual is not a cold sufferer purchaser of Mucinex, and so therefore would not be harmed by higher prices. Nor has Mutual's exclusion from the marketplace harmed competition since Perrigo is alleged to be a competitor. Mutual acknowledges that its rights in the Settlement Agreement are only triggered by the entry of another competitor legally selling Generic ERG in the marketplace. (Compl. ¶ 21.) Mutual thus has not suffered antitrust injury because either it was lawfully excluded by RB's patent under the SA or its contractual rights have been triggered by Perrigo's entry into the market, which would necessarily end RB's monopoly. Mutual thus pled itself out of antitrust standing when it alleged either that RB faces competition from Perrigo or Mutual has no contractual rights. *See City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 264 (3d Cir. 1997).

6. Despite Mutual's misstatements in the opposition brief, Mutual has alleged that RB's monopoly is over. Incredibly, Mutual expressly contradicted its own Complaint when it stated "Today, Reckitt continues to sell its Mucinex products at monopoly prices...." (Opp. Br. at 6.) It follows from Mutual's failure to allege antitrust injury, as opposed to contract damages, that whenever Perrigo began legally selling generic ERG in earnest (whether in 2013 as Mutual alleges or in November 2014, as RB acknowledges) that the price of Mucinex dropped in response. (Compl. ¶ 34, Mov. Br. at 9.) The lawful monopoly RB had over its own patented

product is over, now that a generic competitor has entered the market. For Mutual to state otherwise it must ignore its own allegations, which it cannot do.

II. Mutual's State Law Claims Fail Based upon the Settlement Agreement and Controlling New York Law

Mutual is wrong in instructing the Court to accept Mutual's interpretation of the contracts at issue (Opp. Br. at 20 (this Court must "accept as true" Mutual's "interpretation of the contract.")). Citing nothing in support of this absurd proposition, Mutual has again failed to address controlling Third Circuit precedent. *See, e.g., Trianco, LLC v. Int'l Bus. Machines Corp.*, 271 Fed. App'x 198, 201 (3d Cir. 2008) (finding contract to be an unenforceable agreement to agree under New York law on Rule 12(b)(6) motion, holding "In assessing the sufficiency of Trianco's allegations, we may consider the various documents referenced in the complaint....").

Courts interpret and enforce contracts according to their plain meaning. *In re Nortel Networks Inc.*, 737 F.3d 265, 270 (3d Cir. 2013) ("New York law governs....Thus, the agreement must be interpreted and enforced according to its plain meaning."); *Warnick v. Home Depot U.S.A., Inc.*, 516 F. Supp. 2d 459, 477-78 (E.D. Pa. 2007) (same). Similarly, courts are routinely called upon as here, to confirm the existence of conditions precedent. *Pacific Employers Inc. Co. v. Global Reinsurance Corp. of Am.*, 693 F.3d 417 (3d Cir. 2012). Mutual's failure to address, much less distinguish controlling New York law (Opp. Br. at 18-24) is telling: Mutual failed to plead contractual conditions were complied with, or show that it gave notice of its demand for the right ERG product. The Complaint as pled supports dismissal at this juncture for the further reason that although the SA expressly requires Perrigo to make "legal sales" of its competing Generic ERG as SA ¶5(b)(ii) in order to trigger Mutual's contractual right to demand a Third Party Formulation of the ERG product from RB, the Complaint does not so allege; nor

does the SA establish a configuration or quantity of the product to be supplied exclusively to Mutual. For these reasons and those stated in the moving papers (Mov. Br. at 17-22), RB urges the Court to dismiss the state law claims as a matter of law. *Trianco*, 271 Fed. Appx. at 201.

III. Mutual Has Offered No Justification For Leave To Replead Or The Exercise of Supplemental Jurisdiction

In the second to last line of its brief, without support, Mutual requests that the Court grant it leave to replead its Complaint. Mutual has offered no basis to replead and it has none. Absent any factual basis offered for amending the claims as Rule 15(a) requires, such relief should not be granted. Moreover, since the complaint fails to state a claim as a matter of law under Rule 12(b)(6), repleading would be futile and therefore leave to replead should be denied. *See In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1435 (3d Cir. 1997).

Similarly, there is no basis for this Court to retain jurisdiction of the very claims Mutual saw fit originally to file in state court. But for Mutual's attempt to shoehorn this case into an antitrust framework, Mutual would not have access to federal court. This Court should not reward Mutual's forum-shopping by exercising supplemental jurisdiction. *See De Asencio v. Tyson Foods, Inc.*, 342 F.3d 301, 308 (3d Cir. 2003) (reversing district court for abuse of discretion in exercising supplemental jurisdiction); *Giordano v. City of New York*, 274 F.3d 740, 754 (2d Cir. 2001).

CONCLUSION

For the forgoing reasons and those in the moving papers, this Court should dismiss the Complaint in its entirety with prejudice.

Dated: May 7, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 7, 2015, I caused a true and correct copy of the foregoing Reply Memorandum of Law in Further Support of Motion by Defendant Reckitt Benckiser to Dismiss the Complaint to be served upon the following counsel via the Court's ECF System:

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